

Derek Edgar: Audio CD Script

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Track #1: Nothing Kills a Good Story Like Clinical Results

Hello, and thank you for listening today. I'm Derek Edgar, product manager for revision hips, and over the next several minutes I am going to summarize for you some of the major talking points and issues we've been discussing recently about Zimmer. I would encourage you to listen carefully because there are some outstanding bits of information here that can be real eye openers for those Zimmer-friendly surgeons you've been calling on. I personally have found much of this information to be very timely and useful on sales calls, and suspect that you will too.

Dr. Austin Moore, one of the first US surgeons to perform total hip arthroplasty, once famously remarked that "nothing kills a good story like clinical results." And as we all know, Zimmer is very good at telling what on the surface appears to be a good story on their products. Zimmer continues to benefit from these stories is because surgeons have neither the time nor the inclination to discover what you might call the details.

First, Zimmer has been in business now for about 75 years and had been selling joint replacements for years before Biomet even existed. Yet today, in 2004, Zimmer has just ONE hip with published 10-year follow-up^{1,2,3}. One hip. Considering that Zimmer is at this moment the biggest company in joint replacement products, that is a stunning revelation to say the least. Now, Zimmer did acquire through Centerpulse two hip stems with long-term followup, the Zewymueller and the Spotorno CLS². But these are European designs with mostly European clinical results. Certainly these hips are not the focus of Zimmer's marketing efforts, at least in the United States.

But what IS the main focus of Zimmer's domestic marketing is the Versys family of hips, a system originally brought to market in the 1997-1998 timeframe⁶. In the Versys system, doctors can choose from a whole potpourri of designs, ranging from fully cylindrical, distally-offloading beaded stem that resembles DePuy's AML to a tapered, proximally coated stem kind of like the Mallory-Head primary, to a splined Cobalt Chrome hip that looks similar to DePuy's Replica Hip. None of the Versys hips share a common design philosophy, as they employ different materials, different types of porous coatings, different geometries, and different types of fixation².

One of Zimmer's best sellers, the VerSys Fiber Metal Taper Hip, is actually promoted using clinical results obtained exclusively with Biomet hips. Yes, if you read the marketing literature for the Versys Fiber Metal Taper, they claim that the VerSys is based on "years of successful clinical experience."⁴ To support this claim, Zimmer cites FOUR clinical studies...ALL of them on Biomet hips. Zimmer offers no clinical support for the use of their Versys Fiber Metal taper, and instead points to Biomet's Mallory-Head and Taperloc hips as the very justification for their hips' existence⁴.

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You may then be curious to know precisely what clinical results Zimmer does have on the VerSys hip. Well according to PubMed, there are no long term studies, no medium studies...heck, there aren't even any short term studies⁵. In fact, the only two studies we could find on the Versys pertained to some sort of computer simulated virtual implantation that concluded only that the VerSys appeared to achieve better fixation than Zimmer's own Anatomic hip.⁷

But the newest hip in Zimmer's arsenal, the M/L Taper System, is sure to look familiar to even the untrained eye. Featuring a forged titanium, circumferentially coated, bi-planar taper wedge with the famous A/P indent, the M/L Taper is nearly indistinguishable from Biomet's Taperloc design. In fact, when Zimmer filed for FDA clearance on the M/L Taper, they pointed to Biomet's Taperloc to justify the design and obtain clearance⁸.

Biomet has maintained a consistent design philosophy of a forged titanium, circumferentially coated, bi-planar tapered cementless hip. Why? Because we know that it works. We know that patients who get these hips by Biomet have less osteolysis, less thigh pain, and much better survivorship over the long term compared with other companies' hips and their designs⁹. The evidence for this is clear and is heavily referenced in your clinical comparison brochure. You have four hips in your bag with solid, published long-term clinical followup: the Bi-Metric, the Mallory-Head, the Taperloc, and the Integral. There are only eleven cementless hips on the market today with positive long term clinical followup, and Biomet has four of them⁹. Four out of eleven. That's pretty amazing, and it's pretty inspiring because we have less than 15% market share¹⁰. There are some huge opportunities in front of us, to say the least.

Track #2: PPSTM and the TaperLoc® Hip System

One of the most important differentiating factors for Biomet is our Porous Plasma Spray surface coating. Look at the long-term rates of osteolysis and loosening on cementless stems in the clinical comparison brochure, even the revisions. We believe, as do many clinicians like Dr. Roger Emerson, that our proprietary porous plasma spray technology has played a major role in obtaining bony fixation and preventing osteolysis¹¹. This is a scratch-fit coating with a non-interconnected pore structure that inhibits debris migration while at the same time providing an even distribution of small, medium, and large pore sizes to achieve both short and long term stability. Some people like to claim that our Porous Plasma Spray is "ongrowth only." Well that's just not true. Now there ARE plasma-sprayed surface coatings from other companies that are indicated only for bony ongrowth, but Biomet's Porous plasma spray is indeed an ingrowth surface coating. Zimmer offers a plasma sprayed surface coating on the M/L Taper and the ZMR hip among others, but you should go onto teambiomet and pull up my field communication from April of 2003 entitled "Perception is Reality: Zimmer's ZMR Modular Hip" to see what how a plasma spray surface can fail if it's not done correctly. And keep in mind while you're looking at the photograph of the ZMR pictured in that field comm that this is the same plasma spray coating Zimmer puts on their new M/L Taper Hip.

Speaking of Zimmer's M/L Taper, there are a couple of important issues you should be aware of on this hip. First, this hip is designed with a very high degree of lateral offset¹².

The lateralized Biomet TaperLoc hip is roughly equivalent in lateral offset to the standard Zimmer M/L Taper. Even though more offset seems like a good thing most of the time, too much offset could possibly lead to such problems as nerve palsies, pain, and even trochanteric bursitis^{39,40}. To counteract this significant offset, surgeons may sometimes need to use "minus" heads to get good balance, which may reduce range of motion. And, if a surgeon places the M/L Taper stem into a patient and then decides that it's too lateral or malpositioned, he is advised in the surgical technique to scrap the stem and open a new one due to possible taper damage introduced by the Zimmer extractor instrument¹².

In contrast, you can give your surgeon FIVE clinical studies demonstrating almost unprecedented survivorship in young patient populations, obese patients, and even rheumatoids^{13,14,15,16,17}. There simply is no better story in total hip arthroplasty than the Taperloc.

Track #3: Metal-on-Metal

Now let's move on to an equally interesting topic: metal on metal articulations. For years now, Zimmer has publicly denounced metal on metal by saying that they are not fans of metal on metal, and that they have determined that metal-on-metal is not where they want to be¹⁸. Today, however, with the completion of the Centerpulse acquisition, Zimmer has changed its tune and recently commented that they are very excited about metal-on-metal and that they think it is very strong¹⁹. Even on the Zimmer website at zimmer.com, the company has done an "about-face" and stated that the metal ion release issue is only a theoretical concern used as a commercial argument against companies that do not have the product²⁰.

This new position is certainly in stark contrast to the company's earlier claims. Nevertheless, I would suggest to you that this is a positive development because the only major company in the market without a metal-on-metal articulation is Stryker. My prediction is that the ion release issue will fade into oblivion over the next few years, and so it's time to go on the offensive to sell your metal on metal against Zimmer's on the merits of product performance. If you get stuck on the ion release issue, you really need to pick up the Ion Release whitepaper and get on the ball, especially since we and other industry players expect to be selling ceramic-on-ceramic articulations in the near future. The part number for that ion release whitepaper is Y-BEM-175. But when you're going up against the Zimmer rep on the merits of your product versus theirs, here are some good talking points to keep in mind:

First, all Zimmer has with their Metasul metal-on-metal system is a poly sandwich design; probably not surgeons' first choice. And at the present time the biggest head they have to offer is 32mm, and unfortunately for them, this design limits range of motion to the 120s compared with 154 degrees in the M2a-38 and the 160 degree average available in Biomet's new M2a-Magnum articulation. One consequence of the Metasul system's limited range of motion is early neck impingement⁴¹, which may lead to polyethylene rim wear, notching of the stem after the poly wear-thru, and possibly even metallosis after months or years in the body, thereby requiring revision and fully negating the very benefits the surgeon had hoped to get with the Metasul design. With the recently

launched M2a-Magnum System, with heads sized up to 60mm, it's pretty safe to say you can smoke the Zimmer sales rep in any head-to-head comparison, no pun intended. And if your surgeon prefers a poly sandwich design, of course you have standard and 10-degree M2a-RingLoc liners to bring in. There remains a lot of room to grow metal-on-metal in most markets, and in fact we have several distributors where metal-on-metal is only a very small percentage of their cases. Today, about 1 in 3 articulations sold is metal-on-metal, and we believe there is further upside.

Track #4: Highly Crosslinked Polyethylene

So let's talk now a little bit about highly crosslinked polyethylene. Zimmer has their own original Longevity Highly Crosslinked Poly, and they continue to market Centerpulse's Durasul material. Both have been studied by clinicians and both have published clinical results. Unfortunately, the *in vivo* results so far have been very different from the *in vitro* results that predicted almost no measurable wear at millions of cycles. In fact, in the June 2004 issue of JBJS, a study by Dr. Bradford revealed that at early retrieval, meaning about 10 months out, the Durasul highly crosslinked liners exhibited clear signs of surface damage never seen in simulator studies²¹. Incidentally, these Durasul liners were only available to Dr. Bradford because of the many revised Sulzer Inter-Op shells. But just a few months prior to this paper, back in April 2004, Dr. David Halley and Senior Author Roy Crowninshield reported on a Zimmer Longevity large head articulation with an early poly liner fracture²². The authors emphasize to the reader in this paper that understanding the utility and limitations of these bearing surfaces is of renewed importance²². This is certainly not the type of language that promotes confidence, and you should consider communicating to your surgeons that these reports seem to suggest that the technology in these first-generation highly crosslinked polyethylenes still needs some time to further develop.

Biomet saw the inherent limitations in the early highly crosslinked polys, mostly in terms of their low mechanical strength and high potential for cracking and oxidation. That's why, despite intense pressure, we didn't start marketing a highly crosslinked poly of our own. Now, a few years later, we think our research and development has paid off and we believe we have successfully addressed and overcome the widely reported weaknesses of earlier generations of polyethylene like Longevity and Durasul and have patented our own manufacturing process. In coming months, you will be receiving a comprehensive launch kit on ArCom XL and we expect that like the traditional ArCom polyethylene, Biomet will once again be shown to have the best clinically performing polyethylene on the market.

Track #5: Constrained Liners and Revision Hips

Alright, let's move on and talk a little bit about Zimmer's revision hip product line. They got a pretty unique product in the Centerpulse acquisition called the Epsilon Constrained Liner. This is a very strange-looking design that relies on a partially-encapsulating hood that snaps onto the polyethylene liner over top of the head. You should go to the zimmer.com website and look at the product page, because it is a unique product. The idea behind this is that it constrains the head within the socket, but instead of the ring being circumferential on the outer aspect of the shell, instead it is just a big hood on the

very top and bottom of the shell, the places where the neck is theoretically least likely to impinge. The company claims this design offers very high range of motion, somewhere in the mid-130 degree range²³. But the drawback is evident with just a cursory glance at the surgical technique. Here are three problems.

One, the surgical technique prescribes that the cup be placed at a 55 degree abduction angle²⁴. 55 degrees! That would be considered an extremely open cup, and precisely the type of placement that Dr. Crowninsheild warned in his recent paper could be detrimental to stability in the first place²². If for some reason the surgeon places the cup at less or more than 55 degrees, the large hoods along the circumference of the shell may be at risk for impingement against the neck, limit range of motion, or possibly even lever-out²⁴.

Secondly, assembling the various pieces of the Epsilon apparatus could prove difficult in a revision setting. Placing a standard ring around the poly in a traditional constrained liner like Zimmer's own Trilogy design can be difficult. Now, a surgeon who chooses to use this faces an additional challenge of getting all the components together while also making a determination about whether or not the cup placement is as prescribed.

Thirdly, the Epsilon Constrained Liner polyethylene is Durasul, the same highly crosslinked material that Dr. Bradford noted in JBJS as having cracks at early retrieval²¹. I want you to pay particularly close attention on this point because it's important. In pretty much any constrained liner, there are typically much higher distractive forces trying to pull the head out of the polyethylene socket with each and every step. So, once the patient has bore weight on the leg, the head is then pushed hard against the polyethylene. Conversely, when the patient proceeds to lift the leg off the ground to walk, the musculature may be inadequate and cause the head to come up away the poly liner to a certain extent. This creates a slight piston effect with that constant pushing and pulling. Theoretically, these continuous forces amount to higher fatigue loads on the poly liner.

Compare the Epsilon constrained liner to Biomet's Freedom Constrained Liner. With the Freedom Liner, the surgeon can get an easier surgical technique with no assembly required, an extremely high 110 degrees range of motion, and an equally impressive 200 in lbs of lever-out resistance²⁵. I believe the Freedom may be approaching the number one position in terms of market share for constrained liners because the numbers just keep getting stronger and stronger with each month. The Freedom's five unique liner options, 36mm head, and innovative trialing system have proven to be outstanding selling features and I hope that each and every one of you listening knows this product inside and out.

But now let's spend a minute or two talking about Zimmer's revision stem product offering. Although Zimmer now markets Centerpulse's Alloclassic and Precedent revision hip systems, their flagship product is the ZMR Modular Hip². The ZMR has been around for about 5 years now and features several proximal bodies like a calcar and a tapered shape, as well as splined and porous modular distal stems²⁶. However, Zimmer has not had much clinical success with the product and in fact according to the FDA this

hip was voluntarily recalled due to breakages at the taper junction^{27,28}. In the ensuing aftermath, and the publicized recall of yet another company's modular revision hip system due to breakages²⁹, some surgeons have become leery of using modular hips except when there is no other choice. Roller hardening is a patented manufacturing process that increases the strength of the distal stem taper by 3 times²⁵. All modular stems made by Biomet, 165mm, 300mm, porous, splined, or fluted, all of them today are roller hardened. At the 2003 Academy meeting, you may recall seeing a whitepaper on roller hardening that detailed the manufacturing process and the strength benefit. To counter your story on roller hardening, Zimmer maintains that their titanium nitriding process called Tinidium is an effective method of increasing strength²⁶. But a Tinidium treatment extends only a few microns beneath the surface and offers only a slight hardness benefit and possibly a marginal strength benefit. Whether you believe me or not, the outcomes on the ZMR speak for themselves.

Track #6: Tantalum "Trabecular Metal"

But Zimmer does have one product line that requires a little more creativity to sell against. That's Trabecular Metal, a series of tantalum metal devices that are manufactured into porous shells and tibial trays that appear to offer solid scratch-fit fixation and the possibility of strong bony ingrowth. Certainly there are patients out there who are doing very well with trabecular metal products. And you may at times feel defeated by surgeons who think it's the greatest thing since sliced bread. But my concern with trabecular metal is centered around three core issues. I would ask you to listen closely and consider my case against Tantalum trabecular metal.

First, Tantalum metal has never before been used in a load bearing application. Sure, tantalum has been used in pacemaker leads for years due to its excellent dielectric properties and biocompatibility. But nobody knows if Tantalum, a metal that is weaker than the traditional Ti-6-4 alloy, is susceptible to fatigue cracking or fracture over millions of loading cycles *in vivo*, especially considering the very large pore size in these products.

Secondly, there is a concern in the marketplace about how easily these shells could be revised if, indeed, the bone grew in to the extent marketed by Zimmer. This is a valid concern because infection rates in revision procedures have been reported as high as 17%³². Almost all infected joint arthroplasty patients will undergo another surgery to remove the prostheses.

Third, one has to question the clinical utility of these new devices as it relates to the clinical problems surgeons face. This is the true litmus test. Tantalum is not more biocompatible than titanium or cobalt chrome, as evidenced by several studies, including one published in a field communication in November 2004^{30,31,32,33}. Nor is tantalum any less susceptible to infection. This new metal offers no benefit in terms of achieving a stable joint, nor can the surgeon expect to have an easier surgical procedure. Moreover, the surgeon will not have an easier time obtaining ideal cup abduction and anteversion, and last but not least, Zimmer carries a heavy burden on the question of clinical results. When surgeons see loose acetabular shells, there is almost always a polyethylene wear issue, an infection, or a history of trauma. Trabecular metal addresses none of these

factors as they relate to failed shells. So although these Zimmer products are very intriguing from a product development standpoint, they are more or less meaningless as mainstream products, at least in terms of clinical superiority over the present state of technology. Take control over the facts and force sure your surgeons to justify the use of trabecular metal in cases where you have established alternatives for the entire spectrum of acetabular defects like the McLaughlin +5, the Healey Flanged Shell, the Par 5, the Max-Ti, the Tri-Flange, the Recovery. No other company has the breadth of product in revision hips that Biomet has. I would encourage you to pick up the recent X-Ray Six Pack marketing piece and review the films and listen to the enclosed audio CD. Use these x-rays to showcase the clinical utility of your products and demonstrate how they have been used to help other patients.

Track #7: Minimally-Invasive THA

The last topic of discussion today is minimally invasive hip replacement. Zimmer essentially created this issue a few years ago, with much fanfare and publicity on television, in newspapers, and even in one case, the National Enquirer³⁵. But Zimmer's big push on the 2-incision technique is fraught with challenges.

First, Dr. Hartzband, one of the leading proponents for 2-incision hip replacement, has publicly acknowledged that this procedure is for surgeons doing at least 200 hips per year, a number far exceeding the caseload for the typical orthopedic surgeon³⁶. And just as interesting, Dr. Hartzband, who is a very experienced and talented surgeon, suggested that it took him 100 cases to get comfortable with the technique³⁶.

But putting aside the obvious drawbacks of the 2-incision as it relates to technical skill, there are some more practical problems with it. Indeed, the patient may enjoy smaller skin incisions, but Zimmer promotes a distally-offloading stem for the procedure; the type shown to produce proximal bone loss and thigh pain⁴². It also may require substantially longer OR time and fluoroscopy, which requires the surgeons and staff to don heavy lead vests for the entire procedure. And, if something happens and the surgeon needs to revert to a traditional approach, there really is no good bail out option aside from cutting the patient open with an additional incision.

How fast a patient recovers from surgery is really a secondary concern to the question of how well the implants perform over the long term. Several short term studies have been published on minimally invasive hip replacement, with mixed results^{36,37,38}. In comparison, we have a whole filing cabinet full of long term clinical outcomes on hip components in which the authors recommend which prostheses perform best. Most surgeons out there have over time gone to smaller incisions as a natural part of their surgical technique anyway. Biomet's Microplasty minimally invasive hip instrumentation offers surgeons an advantageous method of gradually reducing incision size without compromising their choice of implant, component placement, or duration of surgery.

Track #8: Summary

We have covered some critical topics pertaining to Zimmer hips here, and hopefully you now have a good understanding of the following four points:

One, Zimmer has either extremely limited or no clinical history on their flagship products, a definitive point of concern for any company, let alone the largest in the world.³

Two, Zimmer's technological innovations have had little clinical significance, as evidenced by the clinical results of such products as titanium nitrided taper junctions in the ZMR hip and trabecular metal acetabular implants.

Three, Zimmer's changed tune on metal-on-metal and intense focus on patient marketing has possibly harmed their credibility in the marketplace, and it affords you the opportunity to redefine the sales focus to issues of clinical outcomes and clinically relevant innovations.

Last but certainly not least, Biomet is poised to enjoy some fresh opportunities in the market with the now-released M2a-Magnum system, the upcoming ArCom XL highly crosslinked polyethylene, the soon to be released Medallion modular revision hip system, and countless other products that are coming your way.

But irrespective of our development efforts at corporate, your bag is already full of high performing, proven products with established track records, like the Freedom Constrained Liner, the Offset Head, the M2a-38, and the Mallory-Head Modular Calcar among others. You can call me, Derek Edgar, anytime at extension 1961 to get additional ideas on selling against Zimmer, or email me at derek.edgar@biometmail.com. Thanks for listening.

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